

# Working DRAFT

## SCRAPIE ERADICATION

State - Federal - Industry  
Uniform Methods and Rules

December 2001

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## **Introduction**

Scrapie Eradication Uniform Methods and Rules (UM&R) are cooperative procedures and standards adopted by Animal and Plant Health Inspection Service (APHIS) and Consistent States for controlling and eradicating scrapie. The UMR is intended to assist State and Federal animal health personnel in implementing the scrapie eradication program consistently and equitably throughout the United States.

This UM&R provides the program standards and procedures for the Cooperative State- Federal- Industry Scrapie Program. They are set up to prevent, monitor, control, and eradicate scrapie disease from domestic sheep flocks and goat herds, and for maintenance of State status in the United States Department of Agriculture (USDA) Scrapie Eradication Program. Flock plan agreements or post exposure monitoring and management plan agreements made prior to the effective date of these standards will remain in force unless changed by mutual agreement.

The contents of this document have been approved by USDA, APHIS, Veterinary Services (VS), and incorporate recommendations from State animal health authorities, and representatives of industry, the National Institute for Animal Agriculture, and the United States Animal Health Association.

This UM&R will be reviewed at least annually by representatives of the livestock industry and appropriate State and Federal Agencies and will be drafted, revised, and published as needed by USDA-APHIS. Also, this UM&R may be amended in the future by replacing pages or by adding new pages.

## **Part I. Definitions**

Any definitions pertaining to scrapie that are published in Title 9, *Code of Federal Regulations* (CFR), Parts 54 and 79 supersede these definitions.

### **Accredited veterinarian**

A veterinarian approved by the Administrator of Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), to perform functions required by cooperative State-Federal animal disease-control and eradication programs.

### **Administrator**

The Administrator of APHIS or any employee of USDA to whom the Administrator has delegated authority to act for the Administrator.

### **Animal**

Any sheep or goat.

### **APHIS**

The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

### **APHIS representative**

An individual employed by APHIS in animal health activities who is authorized by the Administrator to perform the functions and duties involved.

### **Approved laboratory**

A diagnostic laboratory approved by the Administrator to conduct tests for scrapie or genotypes, on one or more tissues.

### **Approved test**

A test for the diagnosis of scrapie that is approved by the Administrator of APHIS for use in the scrapie eradication or certification program.

### **Area Veterinarian-in-Charge (AVIC)**

The veterinary official of APHIS assigned by the Administrator to supervise and perform the official animal health work of APHIS in the State concerned.

### **Breed associations and registries**

Organizations that maintain the permanent records of ancestry or pedigrees of animals (including

the animal's sire and dam), individual identification of animals, and ownership of animals.

**Blackfaced sheep**

Any purebred Suffolk, Hampshire, Shropshire or cross thereof, any non-purebred sheep known to have Suffolk, Hampshire, or Shropshire ancestors, and any non-purebred sheep of unknown ancestry with a black face, except for hair sheep.

**Certificate**

An official document issued in accordance with 9 CFR 79.5 by an APHIS representative, State representative, or accredited veterinarian at the point of origin of an interstate movement of animals.

**Commercial sheep or goat**

Any animal from a flock from which animals are moved only either directly to slaughter or through slaughter channels to slaughter or any animal that is raised only for meat or fiber production and is not registered with a sheep or goat registry or used for exhibition.

**Commingled, commingling**

Animals grouped together having physical contact with each other, including contact through a fence, but not limited contact. Commingling includes sharing the same section in a transportation unit where physical contact can occur.

**Consistent States**

A State, listed in 9 CFR 79.1, that the Administrator has determined conducts an active State scrapie control program.

**Deputy Administrator**

The Deputy Administrator for VS or any other official to whom the Administrator has delegated authority to act for the Deputy Administrator.

**Designated Scrapie Epidemiologist**

A State or Federal epidemiologist designated by APHIS to make decisions about the use and interpretation of diagnostic tests and field investigation data and the management of scrapie affected flocks.

**Destroyed**

- a. Euthanized by means other than slaughter and the carcass disposed of by means authorized by the Administrator; or
- b. In the case of exposed or high-risk animals that are not known to be infected, either euthanized or disposed of by slaughter; or

- c. Moved to a quarantined research facility, if the Administrator has approved the movement.

### **Direct movement to slaughter**

Animals that are transported to a facility for slaughter without unloading en route, other than for food and water, during which the animals are not commingled with any other animals.

### **Electronic implant**

Any radio frequency identification implant device approved for use in the scrapie program by the Administrator.

### **Exposed animal**

- a. Any animal that has been in the same flock at the same time as a scrapie-positive female animal, excluding limited contacts; or
- b. Any animal born in a flock after a scrapie-positive animal was born into that flock or lambled in that flock, if born before that flock completes the requirements of a flock plan; or
- c. Any animal that was commingled with a scrapie-positive female animal during or up to 30 days after she lambled, kidded, or aborted, or while a visible vaginal discharge was present, including during activities such as shows and sales or while in marketing channels; or
- d. Any animal in a noncompliant flock.

### **Exposed flock**

Any flock in which a scrapie-positive animal was born or lambled. Any flock that currently contains a female high-risk or suspect animal, or that once contained a female high-risk or suspect animal that lambled in the flock and from which tissues were not submitted for official testing and found negative. A flock that has completed a post-exposure management and monitoring plan following the exposure will no longer be an exposed flock.

### **Flock / Herd**

All animals that are maintained on a single premises and all animals under common ownership or supervision on two or more premises with animal interchange between the premises. Changes in ownership of part or all of a flock do not change the identity of the flock or the regulatory requirements applicable to the flock. Animals maintained temporarily on a premises for activities such as shows and sales or while in marketing channels are not a flock. More than one flock may be maintained on a single premises if:

- a. The flocks are enrolled as separate flocks in the SFCP; or
- b. A State or APHIS representative determines based upon examination of flock records that:

- No animals have moved between the flocks;
- The flocks never commingle and are kept at least 30 feet apart at all times or are separated by a solid wall through, over, or under which fluids cannot pass and through which contact cannot occur;
- The flocks have separate flock records and identification;
- The flocks have separate lambing facilities, including buildings and pastures, and a pasture or building used for lambing by one flock is not used by the other flock at any time;
- The flocks do not share equipment without cleaning and disinfection in accordance with the guidelines published in the Scrapie Eradication UMR standards.

### **Flock of origin**

The flock in which an animal most recently resided in which it either was born, gave birth, or was used for breeding purposes. The determination that an animal originated in a flock must be based either on the physical presence of the animal in the flock, the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal that is listed on the bill of sale, or other evidence, such as registry records.

### **Flock plan**

A written flock management agreement signed by the owner of a flock, the accredited veterinarian, if one is employed by the owner, and a State or APHIS representative in which each participant agrees to undertake actions specified in the flock plan to control the spread of scrapie from, and eradicate scrapie in, an infected flock or source flock or to reduce the risk of the occurrence of scrapie in a flock that contains a high-risk or an exposed animal. As part of a flock plan, the flock owner must provide the facilities and personnel needed to carry out the requirements of the flock plan. The flock plan must include the requirements in 9 CFR 54.8.

### **High-risk animal**

A sexually intact animal, excluding male sheep that have tested RR at codon 171 and AA at codon 136, that is:

- a. The progeny of a scrapie-positive dam; or
- b. Born in the same flock during the same lambing season as progeny of a scrapie-positive dam, unless the progeny of the scrapie-positive dam are from separate contemporary lambing groups; or
- c. Born in the same flock during the same lambing season that a scrapie-positive animal was born, or during any subsequent lambing season, if born before that flock completes the requirements of a flock plan; or
- d. An exposed female sheep that has not tested QR, HR, or RR at codon 171.

**Inconsistent State**

Any State other than a Consistent State.

**Infected flock**

Any flock in which a State or APHIS representative has determined that a scrapie-positive female animal has resided unless an epidemiological investigation conducted by a State or APHIS representative shows that the animal did not lamb in the flock. A flock will no longer be considered an infected flock after it has completed the requirements of a flock plan.

**Interstate commerce**

Trade, traffic, transportation, or other commerce between a place in a State and any place outside of that State, or between points within a State but through any place outside that State.

**Limited contact**

Incidental contacts between animals off the flock's premises such as at fairs, shows, exhibitions and sales; between ewes being inseminated, flushed, or implanted; or between rams at ram test or collection stations. Embryo transfer and artificial insemination equipment and surgical tools must be sterilized between animals for these contacts to be considered limited contacts. Limited contacts do not include any contact, incidental or otherwise, with an animal during or up to 30 days after she lambed, kidded or aborted or when there is any visible vaginal discharge. Limited contacts do not include any activity where uninhibited contact occurs, such as sharing an enclosure, sharing a section of a transport vehicle, or residing in other flocks for breeding or other purposes, except as allowed by the Scrapie Flock Certification Program standards.

**Live-animal screening test**

Any test for the diagnosis of scrapie in a live animal that is approved by the Administrator as usually reliable but not definitive for diagnosing scrapie, and that is conducted in a laboratory approved by the Administrator.<sup>1</sup>

**Low-risk commercial sheep**

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<sup>1</sup> The names and addresses of laboratories approved by the Administrator to conduct live-animal screening tests will be published in the Notices Section of the *Federal Register*. A list of approved laboratories is also available upon request from the APHIS, VS, National Animal Health Programs Staff, 4700 River Road Unit 43, -Riverdale, MD 20737-1235. State, Federal, and university laboratories will be approved by the Administrator when he or she determines that the laboratory: (a) Employs personnel trained by the National Veterinary Services Laboratories assigned to supervise the testing; (b) follows standard test protocols; (c) meets check test proficiency requirements; and (d) will report all test results to State and Federal animal health officials. Before the Administrator may withdraw approval of any laboratory for failure to meet any of these conditions, the Administrator must give written notice of the proposed withdrawal to the director of the laboratory, and must give the director an opportunity to respond. If there are conflicts as to any material fact, a hearing will be held to resolve the conflicts.



Commercial whitefaced, whitefaced cross, or commercial hair sheep and goats commingled with such sheep that would be low risk goats if they were not commingled with such sheep from a flock with no known risk factors for scrapie, including any exposure to female blackfaced sheep, that are identified with a permanent brand or ear notch pattern registered with an official brand registry or with an official premises ear tag and that are not scrapie-positive, suspect, high-risk, or exposed animals and are not animals from an infected, source, or exposed flock. The term brand includes official brand registry brands on eartags in those States whose brand law or regulation recognizes brands placed on eartags as official brands. Low-risk commercial sheep may only exist in a State where scrapie has not been diagnosed in the previous 10 years in commercial whitefaced, whitefaced cross, or hair sheep that were not commingled with female blackfaced sheep.

**Low-risk goat**

A goat that is not a scrapie-positive, suspect, high-risk, or exposed animal, that has not been commingled with sheep, and that is from:

- a. A State in which scrapie has not been identified in a goat during the previous 10 years;
- b. A State in which scrapie has been identified in a goat during the previous 10 years, but the scrapie-positive goat was not born in the State and resided in the State for less than 72 months and did not kid while in the State; or,
- c. A State in which scrapie has been identified in a goat during the previous 10 years, and the scrapie-positive goat was commingled with sheep, but flock records allowed a complete epidemiological investigation to be completed and all resulting infected, source, and exposed goat herds have completed flock plans and are in compliance with post-exposure monitoring plans.

**Mortgage**

Any mortgage, lien, or other security or beneficial interest held by any person other than the one claiming indemnity.

**National Veterinary Services Laboratories (NVSL)**

The National Veterinary Services Laboratories and its cooperating and contract laboratories.

**Non-compliant flock**

- a. Any source or infected flock whose owner declines to enter into a flock plan or post-exposure management and monitoring plan agreement within 30 days of being so designated, or whose owner is not in compliance with either agreement;
- b. Any exposed flock whose owner fails to make animals available for testing within 60 days of notification, or as mutually agreed, or whose owner fails to submit required postmortem samples;

- c. Any flock whose owner has misrepresented, or who employs a person who has misrepresented, the scrapie status of an animal or any other information on a certificate, permit, owner statement, or other official document within the last 5 years; or
- d. Any flock whose owner or manager has moved, or who employs a person who has moved, an animal in violation of this chapter within the last 5 years.

**Official eartag**

An identification eartag approved by APHIS as being sufficiently tamper-resistant for the intended use and providing unique identification for each animal. An official eartag may conform to the alpha numeric National Uniform Ear-tagging system or another system approved by APHIS, or it may bear an APHIS approved premises identification number that either contains a unique identification number or is used in conjunction with the producer's livestock production numbering system to provide a unique identification number.

**Official genotype test**

Any test to determine the genotype of a live or dead animal that is conducted at either an approved laboratory or at NVSL.

**Official identification**

Identification approved by APHIS for use in the scrapie eradication program.

**Official test**

Any test for the diagnosis of scrapie in a live or dead animal that is approved by the Administrator of APHIS for that use and conducted either at an approved laboratory or at the National Veterinary Services Laboratories

**Owner**

A person, partnership, company, corporation, or any other legal entity which has legal or rightful title to animals, whether or not they are subject to a mortgage.

**Owner statement**

A written statement by the owner that includes the owner's name, signature, address, and telephone number, date the animals left the flock of origin, the premises identification number assigned to the premises, the number of animals, the premises portion of the premises identification if premises identification is used, and a statement that the animals were either born or were used for breeding purposes on the premises to which the premises identification is assigned. (Note: statements for animals that are not identified to their flock of origin that are moved in interstate commerce to a market or slaughter facility where they will be identified must include the name and address of the market or slaughter facility).

**Permit**

An official document issued in connection with the interstate movement of animals (VS Form 1-27 or a State form that contains the same information) that is issued by an APHIS representative, State representative, or an accredited veterinarian authorized to sign such permits. A new permit is required for each change in destination for an animal. A permit lists the owner's name and address; points of origin and destination; number of animals covered; purpose of the movement; whether the animals are from an exposed, noncompliant, infected, or source flock; whether the animal is a high-risk, exposed, scrapie-positive, or scrapie suspect animal; transportation vehicle license number or other identification number; and seal number (if a seal is required). A permit also lists all official identification on the animals covered, including the official eartag number, individual animal registered breed association registration tattoo, individual animal registered breed association registration brand, USDA backtag (when applied serially, only the beginning and the ending numbers need be recorded), individual animal registered breed association registration number, or any other form of official identification present on the animal.

**Post-exposure management and monitoring plan**

A written agreement signed by the owner of a flock, any accredited veterinarian employed by the owner, and a State or APHIS representative in which each participant agrees to undertake actions specified in the agreement to monitor for the occurrence of scrapie in the flock for at least 5 years after the last high-risk or scrapie-positive animal is removed from the flock or after the last exposure of the flock to a scrapie-positive animal, unless otherwise specified by a State or APHIS representative. As part of a post-exposure management and monitoring plan, the flock owner must provide the facilities and personnel needed to carry out the requirements of the plan. The plan must include the requirements in 9 CFR 54.8.

**Premises**

The ground, area, buildings, and equipment occupied by one or more flocks of animals.

**Premises identification**

An APHIS approved eartag, backtag, or tattoo bearing the premises identification number, consisting of the State postal abbreviation or code followed by a unique alphanumeric number or name, assigned by a State or Federal animal health official to the premises on which the sheep or goats originated that in the judgment of the State animal health official or Area Veterinarian in Charge is epidemiologically distinct from other premises, or a permanent brand or ear notch pattern registered with an official brand registry. Premises identification may be used when official individual animal identification is required, if the premises identification method either includes a unique animal number or is used in conjunction with the producer's livestock production numbering system to provide a unique identification number and where, if brands or ear notches are used, the animals are accompanied by an official brand inspection certificate. Paint brands may be used on animals moving direct to slaughter and animals moving for grazing

or other management purposes without change in ownership.

**Program**

The cooperative State-Federal-Industry program administered by APHIS and Consistent States to control and eradicate scrapie.

**Scrapie**

A non-febrile, transmissible, insidious degenerative disease affecting the central nervous system of sheep and goats.

**Scrapie control pilot project**

A pilot project authorized by the Administrator in writing, designed to test or improve program procedures or to facilitate research, in order to control and eradicate scrapie. In addition to APHIS, participants may include State animal health agencies, flock owners, and other parties as necessary.

**Scrapie Eradication Program**

The cooperative State-federal program administered by APHIS and Consistent States to control and eradicate scrapie.

**Scrapie Eradication Uniform Methods and Rules (UM&R)**

Cooperative procedures and standards adopted by APHIS and Consistent States for controlling and eradicating scrapie

**Scrapie Flock Certification Program (SFCP)**

A voluntary State-Federal-Industry cooperative effort established and maintained to reduce scrapie's occurrence and spread; identify flocks that have been free of evidence of scrapie over specified time periods; and contribute to the eventual eradication(formerly known as the "Voluntary Scrapie Flock Certification Program").

**Scrapie Flock Certification Program Standards**

Cooperative procedures and standards adopted by APHIS and State scrapie certification boards for reducing the incidence and controlling the spread of scrapie through flock certification.

**Scrapie-positive animal**

An animal for which a diagnosis of scrapie has been made by NVSL or another laboratory authorized by the Administrator to conduct scrapie tests in accordance with 9 CFR 54, through:

- a. Histopathological examination of central nervous system (CNS) tissues from the animal for characteristic microscopic lesions of scrapie;
- b. The use of protease-resistant protein analysis methods including but not limited to

- immunohistochemistry and/or western blotting on CNS and/or peripheral tissue samples from a live or a dead animal for which a given method has been approved by the Administrator for use on that tissue;
- c. Bioassay;
  - d. Scrapie associated fibrils (SAF) detected by electron microscopy; or
  - e. Any other test method approved by the Administrator in accordance with 9 CFR 54.10.

### **Separate contemporary lambing groups**

To be a separate contemporary lambing group, the group must be maintained separately such that the animals cannot come into physical contact with other lambs, kids, ewes or does or birth fluids or placenta from other ewes or does. This separate maintenance must preclude contact through a fence, during lambing and for 60 days following the date the last lamb or kid is born in a lambing season, and must preclude using the same lambing facility as other ewes or does, unless the lambing facility is cleaned and disinfected under supervision by an APHIS representative, State representative, or an accredited veterinarian between lambings in accordance with the guidelines published in the Scrapie Flock Certification Programs standards and the Scrapie Eradication UM&R. The flock owner must maintain adequate records to document which animals were maintained in each contemporary lambing group and to document when cleaning and disinfection was performed and who supervised it.

### **Slaughter channels.**

Animals in slaughter channels include any animal that is sold, transferred, or moved either (1) directly to a slaughter facility, (2) to an individual for custom slaughter, or (3) for feeding for the express purpose of improving the animals' condition for movement to slaughter. Sexually intact mature female animals as evidenced by eruption of the first incisor that are maintained in the same enclosure with breeding animals from another flock are not in slaughter channels. When selling animals for slaughter, owners should note on the bill of sale that the animals are sold only for slaughter.

### **Source flock**

A flock in which a State or APHIS representative has determined that at least one animal was born that was diagnosed as a scrapie-positive animal at an age of 72 months or less. The determination that an animal was born in a flock must be based either on the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal that is listed on the bill of sale, or other evidence, such as registry records, to show that a scrapie-positive animal originated from the flock, combined with the absence of records indicating that the animal was purchased from outside and added to the flock. If DNA from the animal was previously collected by an accredited veterinarian and stored at an approved genotyping laboratory, or if DNA collection and storage is required for breed registration and the breed registration has appropriate safeguards in place to ensure the integrity of the banking

process, the owner may request verification of the animal's identity based on DNA comparison if adequate records and identification have been maintained by the owner and the repository to show that the archived DNA is that of the animal that has been traced to the flock. A flock will no longer be a source flock after it has completed the requirements of a flock plan.

### **State**

Each of the 50 States, the District of Columbia, the Northern Mariana Islands, Puerto Rico, and all territories or possessions of the United States.

### **State representative**

An individual employed in animal health activities by a State or a political subdivision of a State, and who is authorized by the State or political subdivision to perform the function involved.

### **Suspect animal**

An animal will be designated a suspect animal in accordance with 9 CFR 79.4 if it is:

- a. A sheep or goat that exhibits any of the following possible signs of scrapie and that has been determined to be suspicious for scrapie by an accredited veterinarian or a State or APHIS representative: Weight loss despite retention of appetite; behavioral abnormalities; pruritus (itching); wool pulling; biting at legs or side; lip smacking; motor abnormalities such as incoordination, high stepping gait of forelimbs, bunny hop movement of rear legs, or swaying of back end; increased sensitivity to noise and sudden movement; tremor, star gazing, head pressing, recumbency, or other signs of neurological disease or chronic wasting;
- b. A sheep or goat that has tested positive for scrapie or for the protease resistant protein associated with scrapie on a live-animal screening test, or any other test, unless the animal is designated a scrapie-positive animal;
- c. A sheep or goat that has tested inconclusive or suggestive on an official test for scrapie.

### **Terminal feedlot**

- a. A dry lot approved by a State or APHIS representative or an accredited veterinarian authorized to perform this function where animals are separated from all other animals by at least 30 feet at all times or are separated by a solid wall through, over, or under which fluids cannot pass and contact cannot occur and from which animals are moved only to another terminal feedlot or directly to slaughter; or
- b. A pasture when approved by and maintained under the supervision of the State and in which only non-pregnant animals are permitted, where there is no direct fence-to-fence contact with another flock, and from which animals are moved only to another terminal feedlot or directly to slaughter.

### **Trace**

All actions required to identify the flock of origin or destination of an animal.

**Unofficial test**

Any test for the diagnosis of scrapie or for the detection of the protease resistant protein associated with scrapie in a live or dead animal that either has not been approved by the Administrator or that was not conducted at an approved diagnostic laboratory.

## **Part II. Administrative Procedures**

### **A. Supervision of the Cooperative State-Federal Scrapie Eradication Program**

The Cooperative State-Federal-Industry Scrapie Eradication Program will be supervised by full-time animal health officials employed by the State or the Federal Government.

APHIS may execute a cooperative agreement and/or memorandum of understanding (MOU) with the animal health agency of any State to cooperatively administer the scrapie eradication program within that State.

### **B. Appointing Designated Scrapie Epidemiologists**

The selection and appointment of designated scrapie epidemiologists will be made jointly by the State animal health official and AVIC with the concurrence of the APHIS regional epidemiologist and the APHIS National Scrapie Program Coordinator. (See VS Memorandum 557.3).

### **C. Administrative Review of Program Activities and Progress**

Administrative review of a State's scrapie program will consist of the following:

1. Ongoing review by VS personnel at the local and national levels of program activities and records. Including evaluation of information entered into the Scrapie National Generic Database by State and/or Federal animal health officials in each of the States.
2. Review of epidemiological reports submitted by the DSE(s) in the State to the regional and national scrapie epidemiologist.
3. Review of applications for renewal or reclassification of a State as described in Part IV.
4. Site visits conducted in accordance with VS Memorandum 515.1.



#### **D. Identification and record keeping compliance**

The State must have the authority and take regulatory action to ensure that the following persons maintain records such that it is possible for State or APHIS authorities to trace exposed and/or scrapie positive or suspect animals to all flocks in which they have resided and to determine their final disposition:

- Persons who purchase, deal in, or sell sheep over 18 months of age and/or breeding sheep or goats;
- Persons who act as commission representatives or brokers of such animals; and
- Persons who operate or conduct an auction where such sheep and/or goats are sold.

Action must be taken in the following cases:

- There is adequate evidence to establish that the person had the intent to violate or circumvent record keeping or identification requirements of this section and/or other animal health regulations; or
- The person has repeatedly demonstrated an unwillingness to keep required records or to identify animals, thus impeding the tracing of exposed or scrapie positive or suspect sheep or goats that he or she has handled.

Provisions must exist so that State animal health officials can institute any action at law or in equity that appears necessary to enforce compliance with animal identification and record keeping requirements under this UM&R. Possible actions include the authority to subpoena appropriate records and/or persons who allegedly violate these standards. The appropriate State officials must also have authority to petition the local court that has jurisdiction for an order to enforce these subpoenas.

#### **E. Requirements for program personnel entering premises**

Persons working on the Scrapie Eradication Program must be employees of the State or APHIS or be authorized by the State or APHIS to carry out Program procedures. While on those premises, they must use sanitary procedures to minimize the risk of physically transmitting scrapie or other diseases to other premises.

#### **F. Exceptions to the Deadline(s)**

Program officials must follow deadlines for the flock plan, investigation, and testing except when a designated scrapie epidemiologist determines that there are extenuating circumstances. The extenuating circumstances must make it impossible to meet the

deadline established for a particular flock. The designated scrapie epidemiologist must immediately set a new deadline in consultation with the flock owner or his or her representative. The new deadline must be consistent with the principles of the scrapie eradication program.

#### **G. Flock Depopulation**

State or Federal officials of the Scrapie Eradication Program will review sheep and/or goat flocks for depopulation, with indemnity, based on the prevalence and epidemiology of the infection. In States that have been classified as free of scrapie, all affected flocks must be reviewed for possible depopulation with indemnity.

#### **H. Indemnity**

##### **Animals eligible for federal indemnity payments**

Federal Indemnity may be paid for an animal only after the owner of the animal has applied for indemnification and been approved in accordance with 9 CFR 54.4. Federal Indemnity may be paid only for the following:

- Destruction of high-risk animals;
- Destruction of animals based on an epidemiological investigation, when the authorized APHIS representative determines that destroying these animals will contribute to eradicating scrapie;
- Destruction of live scrapie-positive animals;
- Destruction of animals that test positive on a live-animal screening test;
- Destruction of suspect animals that are destroyed at the request of an APHIS representative.

##### **Requirements of flock owners to receive indemnity**

Before any indemnity is paid to an owner, the owner must be in compliance with the flock clean-up and monitoring plans including the provision or release of all requested records.

##### **Amount of indemnity payments**

Federal indemnity: Federal indemnity will be paid in accordance with 9 CFR 54 and will be based on price reports provided by the Agricultural Marketing Service (AMS) as described in 9 CFR 54.6. Spreadsheets will be provided to Federal and State representatives to assist with calculation of indemnity.

State-Industry Indemnity: State and or Industry indemnity may be paid in addition to Federal indemnity in accordance with State Regulations and industry guidelines up to

the fair market value of the animal

**Indemnity procedures for animals destroyed.**

Animals for which indemnification is sought must be destroyed in accordance with 9 CFR 54.7. Animals that are not scrapie-positive or suspect animals for which indemnification is sought may be slaughtered when moved in accordance with 9 CFR part 79 and with the prior written approval of the APHIS representative involved. The destruction of animals and disposition of their carcasses must be monitored by an APHIS representative. State personnel may conduct or supervise these activities including signing the valuation portion of the VS Form 1-23 when authorized by and monitored by APHIS. The AVIC must review and sign the VS Form 1-23. APHIS may pay, when approved in advance in writing, the reasonable and customary costs of disposal for scrapie positive and suspect animals. The owner of the animals must present to APHIS a copy of either a receipt for expenses paid or a bill for services rendered.

**I. Permits**

A permit is required for movement of high risk, suspect, scrapie-positive and some exposed animals.

**J. Records of terminal feedlots**

Records of all animals entering and leaving a terminal feedlot must be maintained for one year after the animal leaves the feedlot and must include the person from whom the animals were acquired and the slaughtering facility in which they were slaughtered. Records must be made available for inspection by an APHIS or State representative.

**K. Movement Restriction Release Procedures and Criteria for Releasing Infected or Source Flock Status**

No sexually intact animal should be permitted to move from an infected or source flock except under permit either to slaughter, to a terminal feed lot, or to an APHIS-approved research or diagnostic facility until a standard or pilot flock plan agreement has been signed. The movement restrictions on the flock and criteria for release of these restrictions should be specified as part of the flock plan and post exposure and monitoring and management plan. Sheep from flocks on approved pilot project flock plans written in accordance with 9 CFR 54 that are not high risk, scrapie-positive, or suspect animals, may be moved under the terms specified in the plan which must meet or exceed the 9 CFR requirements for exposed animals.

- High-risk animals must be retained on the premises unless the animal is moved under

- permit to slaughter or to a research or diagnostic facility and should be submitted for testing when they die.
- Exposed animals may be moved only as permitted under 9 CFR and State regulations.
  - Animals that do not meet the definition of exposed are generally free to move unrestricted once the flock plan is completed; however, pilot flock plans and standard flock plans should restrict genetically more susceptible animals in cases where heavy premise contamination was likely to have occurred or where adequate cleaning and disinfection of lambing areas was not possible.

#### **L. Scrapie National Generic Database (SNGD) - Data Entry Requirements**

Complete information is available to data entry persons in the SNGD tutorial.

##### **Information that must be entered**

Each premises or person that either (1) is or has been enrolled in the SFCP, (2) is or has been designated an infected, source, exposed, or non-compliant flock, (3) owns or has an exposed, high risk, suspect, or scrapie positive animal residing there, or (4) has been issued a premise identification number for use as official identification such as eartags, backtags, or tattoos or has been issued tags must have a premise form accurately completed and maintained in the SNGD. Note: The Flock ID must be completed in user field 1 of the premises supplemental form.

Each serial of numbers assigned to a person for use as on official identification such as eartags, backtags, or tattoos and each serial of tags issued must be accurately recorded and maintained in the miscellaneous form of the (SNGD).

Each animal that has been designated scrapie positive, suspect, high risk, or exposed or that resides in an infected, source, or exposed flock must have an individual animal record completed and maintained in the (SNGD). Individual records should when practical be completed and maintained for animals in SFCP flocks.

A test record must be completed and maintained for each animal that is tested for scrapie or for genetic susceptibility to scrapie.

## **Part III. Identification requirements**

### **A. Identification of sheep and goats in commerce**

#### **Identification Requirements**

Animals required to be identified in 9 CFR 79.3 shall be officially identified upon change of ownership to its flock of origin (flock in which an animal most recently resided for breeding) and its flock of birth using one of the methods provided in 9 CFR 79.2.

The animals required to be identified include:

- All breeding sheep;
- All sexually intact animals for exhibition;
- All sheep over 18 months of age;
- All exposed, suspect, test positive and high risk animals;
- Breeding goats, except low risk commercial goats.

See 9 CFR parts 79.2 and 3 for specific interstate requirements and restrictions.

#### **Issuance of premises identification numbers**

The Area Veterinary Services Office or the State Veterinarian's office will issue a premises identification number to each sheep or goat owner who requests a number. The office will fill out a premises information form in the Scrapie National Generic Database and permanently assign a premises number and a premises identification number that will be used on tags or as the premises portion of the tattoo; in some States the numbers will be the same.

All two and three character alphabetical sequences must be reserved for use by producers who use registered tattoo prefixes. All two and three character numeric and alphanumeric sequences must be reserved for flocks that participate in the SFCP or that tattoo. When possible, the premise identification number for premises with registered tattoo prefixes will be the postal abbreviation followed by the producer's registered tattoo prefix. Alpha and alphanumeric sequences that contain I, O, or Q may not be assigned.

#### **Allowed tags**

Only USDA provided or approved tags shall be used. USDA provided tags will either have a unique alphanumeric sequence, or a premises number and a production (animal) number that is unique within a flock, or a premises number and a unique alphanumeric sequence. The premises number will be the State Postal abbreviation followed by up to five alphanumeric digits. All tags will have the U.S. shield. Premises tags produced by approved tag companies will have the premises number

and a unique production number.

Series of alphanumeric USDA eartags and backtags may be assigned as premises identification if they are linked to the premises in the Scrapie National Generic Database.

**Issuance of Official Identification tags to persons other than producers**

The Area Veterinary Services Office or the State Veterinarian's office for the State in which that person maintains his or her place of business shall assign a person number to each accredited veterinarian or regulatory person and a premises identification number to persons who handle sheep and goats in commerce and shall issue official USDA serial number backtags or ear tags to these persons when requested.

The official responsible for issuing ear tags in a State may assign serial numbers of official eartags to other responsible persons, if the State animal health official and the AVIC agree that such assignments will improve scrapie control and eradication within the State, and if appropriate records are maintained to permit traceback of animals to the flock of origin and its flock of birth.

**The owner of the flock of origin is the primary person responsible for officially identifying animals**

The owner of the flock of origin or his agent must officially identify any animal that requires official identification prior to commingling them with animals from a different flock of birth or origin such that sheep or goats are identified to their flock of origin and flock of birth.

Producers are strongly encouraged to officially identify their animals before they leave their premises whenever it is practical to do so to prevent any error from occurring in the later identification of the animals and to assure that they will meet the interstate movement requirements.

If official identification has not been placed on the animal by the owner prior to leaving the premises of origin, the owner must ensure that the animal is officially identified before it is commingled with an animal from a different flock of origin.

**Responsibility of persons handling sheep and goats in commerce to identify animals**

A person who delivers an animal that is required to be identified to a place where it will be commingled must ensure that it is officially identified to its premises of origin prior to commingling.

A person who receives an animal that is required to be identified at a site where it will be commingled must ensure that it is officially identified to its premises of origin prior to

commingling.

A person cannot move animals lacking the required identification which have been commingled unless they are identified in accordance with 9 CFR part 79.2(a)(3) (this section requires that all possible flocks of origin be recorded).

### **Premises and Individual Identification**

Premises identification may be used as official individual animal identification, if the premises identification method either includes a unique production number or is combined with a flock eartag that has a unique production number. Official individual animal identification may be used as premises identification if the tag numbers have been assigned to the flock of origin by a State or Federal animal health official and have been linked to the premises of the flock of origin in the Scrapie National Generic Database, and the animals are accompanied by an owner statement.

### **Restrictions on the application of premises identification**

No person shall apply a premises identification number or a brand or ear notch pattern to an animal that is not from the flock of origin to which the number was assigned by a State or APHIS representative or to which the brand or ear notch pattern has been assigned by an official brand registry. This includes individual identification such as USDA tags and backtags that have been assigned to a premises for use as premises identification and registration tattoos that contain prefixes that have been assigned to a premises for use as premises identification. An owner may apply his assigned premises identification to an animal that has resided on his premises for breeding purposes but must record the previous flock of origin information if it was not born in his flock.

States may assign premises type numbers for use by persons other than flock of origin owners if there are State regulations that make it possible to trace animals so identified to their flock of origin and birth.

### **Records of animals handled - General requirements**

Each person who buys or sells, for his or her own account or as the agent of the buyer or seller, transports, receives for transportation, offers for sale or transportation, or otherwise handles sheep or goats in interstate commerce must ensure that animals are identified as required and must keep records relating to the transfer of ownership, shipment, or handling of the sheep or goats, such as yarding receipts, sale tickets, invoices, and waybills (Note: Transporters who do not own the animals they transport are only required to retain normal business records and to have required documents while actually transporting the animals).

### **Records required to be kept by persons who acquire animals that are identified to their flock of origin.**

- Number of animals acquired;
- The date of purchase or acquisition;
- Name, address and phone number of the person from whom they were purchased or otherwise acquired.

Additional records required include:

- *Animals not in slaughter channels* - If the animals are not in slaughter channels, the records must also include either the individual numbers on the animals or their premise identification number;
- *Animals with registered brands or ear notches* - If registered brands or ear notches are used, the records must also include a copy of the brand inspection certificate.

#### **Records required of persons who sell or dispose of animals that are required to be identified and that are identified to their flock of origin**

- Number of animals sold or disposed;
- The date of sale;
- Name, address and phone number of the buyer or person who acquired the animals.

Additional records required:

- *Animals not in slaughter channels* - If the animals are not in slaughter channels, the records must also include either the individual numbers on the animals or their premise identification number;
- *Animals with registered brands or ear notches* - If registered brands or ear notches are used, the records must also include a copy of the brand inspection certificate.

Note: Animals that are not officially identified to their premises of origin may not be disposed of in interstate commerce.

#### **Records required of persons who officially identify animals**

Persons who apply official identification assigned directly to the owner of the premises of origin of the animal in the National Scrapie Generic Database (SNGD) must record:

- Date officially identified
- Number of sheep and number of goats identified
- Premises number or serial numbers applied
- If born after January 1, 2002 in another flock and not already identified to flock of birth, the name, address, and phone number of the owner of the flock of birth.

Note: While this is the minimum that must be kept, the producer will have an easier time completing a flock cleanup plan if a positive animal is traced to his flock if the identification



number applied is linked to any breeding or other information that he has on the animal.

Persons such as veterinarians, dealers, or markets who apply official identification that is not assigned to the owner of the premises of origin of the animal in the SNGD must record the following for animals that have official identification not linked to the current flock of origin:

- Date tagged;
- Number of sheep and number of goats identified;
- Serial numbers applied;
- Flock of origin owner's name, address, and phone number and premises number if known and if different the person requesting identification.

Note: Animals with official ID linked to the current flock of origin do not need to be tagged again

Persons such as veterinarians, dealers, or markets who apply official identification that is not assigned to the owner of the premises of origin of the animal in the SNGD must record the following for animals without official identification:

- Date tagged;
- Number of sheep and goats identified;
- Serial numbers applied;
- Flock of origin owner's name, address, and phone number and if different the person requesting identification;
- If different flock of birth owner's name, address, and phone number for animals born after January 1, 2002.

Note: If the flock of birth of these animals is unknown, a slaughter only tag must be applied and animal moved in slaughter channels only.

Note: Animals that lose official identification may be retagged if all possible flocks of origin are listed in the record of identification applied.

### **Keeping of records**

Each person required to keep records under this paragraph must maintain the records for at least five years after the person has sold or otherwise disposed of the sheep or goat to another person, and for such further period as the Administrator may require by written notice to the person, for purposes of any investigation or action involving the sheep or goat identified in the records. The person must make the records available for inspection and copying during ordinary business hours (8 a.m. to 5:30 p.m., Monday through Friday) by any authorized

USDA or State employee, upon that employee's request and presentation of his or her official credentials.

#### **Restrictions on the removal of Official Identification**

No person may remove or tamper with any approved means of identification required to be on sheep or goats in accordance with 9 CFR 79 while the animals are in interstate commerce. At the time of slaughter, animal identification must be maintained throughout postmortem inspection in accordance with regulations of the Food Safety Inspection Service.

#### **Loss of ability to apply Official Identification**

Any person who fails to comply with these requirements shall not be assigned serial numbers of USDA backtags, official sheep and goat tattoos, official eartags, or premises identification numbers.

### **B. Scrapie Suspect, Positive, Exposed, Low exposure, or High Risk Animal(s) Identification**

1. ID Type is an official metal eartag.
  - a. Animals that are permanently restricted to the premises or that may be moved only under permit will be identified with an official yellow metal tag. Animals not requiring a permit for movement to slaughter will be identified with an official metal tag marked "for slaughter" or "meat" or an official yellow metal eartag.
  - b. Animals that are positive on an official live animal test will be identified with a red metal tag.
  - c. Only APHIS or State representatives may acquire yellow or red metal tags.
2. Tag Application shall be by an APHIS representative, State Animal Official, or an accredited veterinarian.
3. Prohibitions:
  - a. Tag removal
  - b. Movement except in accordance with 9 CFR 79
  - c. Movement, slaughter, destruction, or disposal of the animal or carcass without written approval of an APHIS or State representative.
4. All forms of identification on suspect, positive, exposed, low exposure, high risk animals shall be recorded on a VS Form 5-20 and forwarded to the Designated Scrapie Epidemiologist.

## **Part IV. Shows and Sales**

Official identification is required for any sexually intact animal to be exhibited.

All female animals over 12 months of age as evidenced by eruption of the first incisor shall be housed in separate enclosures from animals from different flocks. All animals from SFCP enrolled flocks must be housed and handled such that direct contact does not occur with animals from other flocks of lower status. Spacing or solid partitions may be used to maintain separation. Stalls should be thoroughly cleaned before use by an animal from another flock.

If sheep or goats that are within 30 days pre- or post-parturition or have a vaginal discharge are allowed at a show, special arrangements shall be made to keep them separate from animals from different flocks and in an area that can and will be properly disinfected, unless the animals are low risk goats.

## **Part V. Program Stages**

### **A. Standards for State Programs to Qualify as Consistent**

Consistent State status is granted to qualified States by the Administrator in accordance with 9 CFR 79.6.

### **B. Program Stages for Consistent States or Zones to Reach Free Status – (This section is under development and will remain open for further comment and consideration).**

**Consistent Stage I** - Meets the requirements for a consistent State or zone and conducts surveillance at a rate that gives 95 percent confidence of detecting 0.1 percent scrapie prevalence in animals that are showing signs of a neurological or wasting condition. Successfully traces 95 percent of all suspect and test positive animals at slaughter to their flocks of origin and their flocks of birth. Does complete epidemiological investigations of each exposed, infected, and source flock identified. Takes actions as specified in this UM&R to clean up and monitor these flocks. All flocks requiring flock plans are in compliance with a flock plan or have been restricted with movement only to slaughter under permit.

**Consistent Stage II** - Has met Stage I requirements for at least 12 months and has had a prevalence of less than 0.1 percent during that time. Prohibits the use of embryos from infected and source flocks, and infected animals. Permits entry of female animals and embryos only from Stage II or higher States, zones, countries, or from certified free flocks. Permits entry of male animals only from Consistent or higher stage States, zones, or countries, or from certified free flocks. These entry restrictions do not apply to wethers, animals for immediate slaughter, or for feeding in a terminal feedlot.

**Consistent Stage III** - Continues to meet Stage I requirements, and has met Stage II requirements for at least 12 months and has had no cases in animals born in the State or zone in the preceding 12 months. If there is a case in the State or zone in an animal that was born in another State or zone, or if an exposed or high-risk animal is traced to the State or zone, all the exposed animals in the State or zone were located, destroyed, and, if exposure to other animals has occurred, submitted for diagnostic testing. Prohibits animals and embryos from animals that have been exposed to scrapie or that were born in an exposed flock. Prohibits semen from infected and source flocks and infected animals. Permits entry of animals and embryos only from (1) Stage III or higher States, zones, or countries and (2) certified free flocks. These entry restrictions do not apply to wethers, animals for immediate slaughter, or for feeding in a terminal feedlot. Pastures may not be approved as terminal feedlots and terminal feedlots may not accept exposed or high-risk animals.

**Scrapie Free** - Has met Stage III requirements for at least 72 months and has had no cases in

animals born in the State during the preceding 72 months. Prohibits animals and embryos from animals that have been exposed to scrapie or that were born in an exposed flock. Prohibits semen from infected and source flocks and infected animals. If there is a case in the State or zone in an animal that was born in another State, or if an exposed or high-risk animal is traced to the State or zone, all the exposed animals were located and destroyed and submitted for diagnostic testing. Permits entry of animals and embryos only from Free States, zones, or countries and certified free flocks. These entry restrictions do not apply to animals for immediate slaughter or for feeding in a terminal feedlot. The State or zone must establish procedures for preventing the movement of such animals out of slaughter channels. Pastures may not be approved as terminal feedlots and terminal feedlots may not accept exposed or high-risk animals.

### **C. Scrapie Classification, Renewal, or Reclassification of a State or Zone**

**Purpose:** This application is for the annual classification, classification renewal, or reclassification of a State for national scrapie status recognition.

**Data Source:** Area and State Offices, and the SNGD.

**Action:** A completed VS Form 5-24 application and report must be filed by the VS Area Office for each State annually. The completed VS Form 5-24 should be submitted to the National Animal Health Programs Staff through the regional scrapie epidemiologist within one month after the due renewal date. The application must be signed by both the State Veterinarian and AVIC. The required data includes certification statements and reports on sheep flock and goat herd monitoring and testing results in the State; the number of positive, high-risk, exposed and suspect animals; quarantines or movement restrictions issued (if any) and release dates; slaughter test results; animal trace-backs; a brief summary of the history of scrapie in the State; and success in the identification of sheep and goats.

**National Level:** The Chief Staff Veterinarian and the National Scrapie Program Coordinator of the National Animal Health Programs Staff (NAHPS) will review all VS Form 5-24 applications for completeness to determine if the State meets the requirements in accordance with current Federal regulations (9 CFR, Part 79) and the Uniform Methods and Rules for Scrapie Control and Eradication. If the State meets all the necessary conditions, the Chief Staff Veterinarian (NAHPS) will approve the status for another year and issue a new reporting date in a letter to the AVIC and the State Veterinarian. In cases that involve a change in status the Chief Staff Veterinarian will refer the application for review and comment by the Scrapie Control Board. APHIS will publish changes in status in the Federal Register as an interim rule.

## **Part VI. Monitoring and Surveillance**

### **A. Scrapie Flock Certification Program**

Individual copies of the Scrapie Flock Certification Program standards may be obtained on the World Wide Web at <http://www.aphis.usda.gov/vs/scrapie>, or from the APHIS, National Animal Health Programs Staff, 4700 River Road Unit 43, Riverdale, MD 20737-1235.

### **B. Slaughter and Market Surveillance**

#### **Suspect animals at markets or slaughter facilities**

Clinically suspect and test positive animals may not be moved from the premises where identified except under permit to a research facility designated by APHIS, to a site for destruction, or, when appropriate, to the flock of origin for quarantine. Such animals should be placed under movement restriction until an investigation can be done. If the investigation concludes the animal is a scrapie suspect, the animal should either be purchased for diagnostic purposes and necropsied or maintained under restriction until it either recovers and is released or dies and is necropsied.

Clinically suspect animals at slaughter facilities must be condemned in accordance with Food Safety Inspection Service regulations and reported to the AVIC so that samples can be collected for diagnosis and the carcass removed from the food chain.

Regarding routine slaughter sampling, see requirements for States to progress in the program and the Scrapie Ovine Slaughter Surveillance handbook.

### **C. Live Animal Surveillance Testing**

States may pilot live animal sampling programs for at risk populations on farms, at markets, or as a condition to participate in a sale in areas of high scrapie prevalence or in high prevalence classes within an area. Movement beyond the pilot stage will be based on the relative cost of identifying new infected flocks through the piloted method as compared to slaughter surveillance.

## **Part VII.        Epidemiology**

### **A. Required steps for conducting an epidemiological investigation for scrapie in a flock or herd**

- a. Follow up of a report of a clinically suspicious animal to a State or APHIS representative
- b. The flock is assigned a number and entered on the Scrapie National Generic Database as a premises if it has not already been entered. A status record will be created that lists the flock status as investigation (INVEST) with the reason for the investigation status suspect (SUSPECT).
- c. APHIS and State animal health officials are notified.
- d. The flock owner is contacted by a regulatory Veterinary Medical Officer (VMO) and the animal restricted by an authorized representative of the State. The owner will be given information about scrapie and a premises visit will be scheduled for a VMO to examine the animal and conduct an investigation as soon as possible but within seven days. The owner advised not to remove or dispose of the suspect animal (or other animals that may display evidence of disease) and to report immediately if its condition worsens or it dies.
- e. If the VMO determines that the clinical signs are compatible with scrapie, with the owners consent, euthanasia and necropsy will be arranged. The animal may be purchased for diagnostic purposes.
- f. If the signs are consistent with scrapie but other causes are still being considered, the VMO should require that the animal be held for observation. The owner should be advised to isolate the suspect animal from other animals in an area that can be cleaned and disinfected. If the owner requests, humane considerations justify it, or the clinical signs of scrapie persist, the animal will be euthanized. If it is euthanized or dies, it must be necropsied and tissues submitted for testing at NVSL. If the owner elects to hold the animal for observation, movement restrictions will be maintained on the animal. Written instructions will be given to the owner regarding the restrictions and providing contact information in the event that animal becomes worse or dies. The owner must be advised in writing that his flock status will be jeopardized if he fails to promptly request a necropsy if the animal dies or if he moves the animal without a permit. The animal should be inspected at least every four weeks until it can be determined whether the animal has scrapie and to monitor for compliance with the movement restrictions. Severely affected animals should be monitored more frequently. If it becomes clear on inspection by a VMO that the animal does not have scrapie, the movement restrictions will be lifted and the investigation status closed in the Scrapie National Generic Database.

- g. The owner of suspect animals that are not euthanized shall be offered third eyelid testing in accordance with USDA policy.
- h. An individual animal record is created in the Scrapie National Generic Database and if the animal is necropsied or third eyelid tested a test status is also opened in the Database. (See the Scrapie National Generic Database scrapie tutorial for additional data entry instructions and the APHIS Scrapie Necropsy Guide for tissue collection instructions).
- i. Additional restrictions will be imposed on the flock if the clinical signs are typical of scrapie pending results of an official test.

## **B. Follow up of a report of live test positive animal**

- a. APHIS and State animal health officials are notified.
- b. If the flock does not already have an assigned premises number it is assigned a number and entered in the Scrapie National Generic Database as a premises. A status record, with status, INVEST, and reason, SUSPECT, is generated. (See Scrapie National Generic Database Tutorial for data entry instructions).
- c. If the test was an official test, the flock will be handled as in (d). If the test was an unofficial *APHIS sponsored* test the animal will be purchased under the provisions of the APHIS live animal test agreement.
- d. If the test was an unofficial test:
  - i. The animal will be classified as a suspect in accordance with 9 CFR Part 79 and Part VI.a.1.
  - ii. The owner will be offered third eyelid testing in accordance with APHIS policy.
  - iii. The suspect designation of an animal may be removed by the DSE for any of the following reasons:
    - If the animal is not showing clinical signs of scrapie, is over 18 months of age, and is negative on an APHIS sponsored third eyelid test;
    - An epidemiological investigation shows the animal not likely to be infected and an APHIS sponsored third eyelid test cannot be done due to lack of sufficient tissue. After all factors are weighed, and there is a significant concern that the animal may be at risk of having scrapie, the animal should either be purchased for diagnostic reasons and necropsied, or held for observation.
  - iv. An individual animal record is created in the Scrapie National Generic Database and if the animal is necropsied or third eyelid



tested a test status is also opened in the Database. (See the Scrapie National Generic Database Tutorial for additional data entry instructions and Appendix F for necropsy tissue collection instructions).

- v. Additional restrictions will be imposed on the flock if the clinical signs are typical of scrapie pending results of an official test.

**C. Procedure following receipt of results from NVSL confirming a scrapie positive animal.**

- a. NVSL will inform the VS Area Office that a tissue submitted for scrapie testing was positive by an official scrapie test. Appropriate State officials are informed by the AVIC. The Area Office will notify the DSE and assign a VMO to conduct an epidemiological investigation or will refer the case for investigation by a State VMO. The investigation status is released in the Scrapie National Generic Database for the flock and the status pending designation (PDESIG) is opened.
- b. The VMO will contact the owner and arrange a visit within seven days of notification. During the initial visit, the owner will be informed about the results of the diagnostic tests and his/her responsibilities under the Program and is provided with information about scrapie and its control. The flock will be inspected and the identity of the animal and flock will be confirmed. A VS Form 5-19 will be completed and a State order written restricting animal and embryo movement from the premises. Information required for the epidemiologist's report will be collected. All animals will be officially identified and an inventory of all animals and embryos will be attached to the hold order. A copy will also be attached to the epidemiology report.
- c. The information about the flock is provided to the Designated Scrapie Epidemiologist (DSE) for review. The DSE determines the status of the flock. The DSE may request additional testing of the flock to determine the flock's status. If the flock does not meet the definition of an infected or source flock, the pending designation status is closed. If the flock meets the definition of a source or infected flock, the pending designation status is closed and an infected or source status and a hold status are opened. If the owner has signed a flock plan and the flock is under State movement restrictions, the infected or source status may be closed and a plan status opened. (Note: the flock is still considered an infected or source flock until the flock plan is completed and the plan status released. The infected or source status will be reopened if the flock does not complete the flock plan in a timely manner or is found not to be in compliance with the plan. All actions that are under the control of the flock owner should be completed within 30 days).

- d. The Area Office sends an official notification of designation of infected and/or source status to the owner of the flock under investigation by mail as required by CFR 9, part 79. All animals in the flock are entered into the Scrapie National Generic Database animal sample information. Each animal must be classified as suspect, high risk, scrapie positive, or exposed. An event entry is made for the inspection.
- e. If the positive animal was not born into the flock and was diagnosed as scrapie positive at an age of 72 months or less, the source flock must be determined. If the flock of birth is in the same VS Area a pending designation status is opened for the birth flock and an investigation is initiated. If the birth flock is out of the VS Area, notification must be made to the AVIC of the other Area as soon as possible, but no later than 45 days. The receiving Area office will initiate the data entry and the investigation for the birth flock and proceed as in (b).
- f. If the positive animal is a female over 12 months of age that has not resided in the flock for its entire adult life, an investigation must be conducted to determine if it has lambed in any other flock. If such a flock is identified, that flock is designated infected and handled as such.
- g. The epidemiology report includes information about the positive animal, the flock and movement of animals into and out of the flock. The flock inventory will include identification numbers, sex, breed, birth date, flock of origin, and date of acquisition. The management and health history of the flock will be described. The information is used to determine which animals are classified high risk or exposed, and where possible exposed, infected, and source flocks may be located. (See Appendix D for detailed instructions for completing the epidemiological investigation report).
- h. A flock plan will be prepared by the VMO in collaboration with the owner and the owner's veterinarian and in accordance with the requirements of 9 CFR 54 and Veterinary Services Notices and memorandums. The DSE shall review and approve the flock plan. High-risk animals to be removed are specified in the flock plan. Cleaning and disinfection requirements are specified. (Cleaning and disinfection procedures are listed in the Appendices). If the infected animal was not born in, and did not lamb in, the flock, cleaning and disinfection can be waived. A post-exposure monitoring plan is selected consisting of either a post-exposure monitoring and management plan or enrollment in the SFCP and meeting the requirements for exposed flocks for five years.
- i. The flock plan and the post-exposure monitoring and management plan or SFCP application is signed by the flock owner and State official and/or APHIS officials (depending on the delegation of duties within the State). An entry in the Scrapie National Generic Database is made to add the status plan. Plan status means that a

plan has been signed and the owner is in compliance with the plan. All high risk, exposed, suspect, and all animals under the plan are also entered in Scrapie National Generic Database animal sample information form.

- j. The VMO verifies that the flock plan requirements are completed, at which time, some or all of the movement restrictions may be removed and the flock's plan status is released. In the Scrapie National Generic Database, the infected, hold (hold may remain in place if a non-standard plan is used), and plan statuses are released. A new status is entered status = peplan to indicate that the flock is on a monitoring plan.
- k. High risk and exposed animals no longer in the flock are traced to their current owners within 45 days. The Area Office sends an official designation of high risk animal, exposed animal, and/or exposed flock status to the owner by mail as required by 9 CFR, part 79. If the animals are located in another State, the area office informs the AVIC in charge of that State by e-mail and letter as soon as possible, but no later than 45 days. That AVIC is responsible for the steps listed in (D).

**D. Actions that must be taken when an exposed or high-risk animal is traced to a flock that has not been designated an infected or source flock.**

- a. The flock is assigned a number and entered on the Scrapie National Generic Database as a premises if it has not already been entered. A status record will be created that lists the flock status as investigation (INVEST) with the reason for the investigation status exposed or high risk.
- b. APHIS and State animal health officials are notified.
- c. The flock owner is contacted by a regulatory VMO and the animal(s) restricted by an authorized representative of the State. The owner will be given information about scrapie and a premises visit will be scheduled for a VMO to examine the animal(s) and conduct an investigation as soon as possible but within seven days. The owner should be advised to report immediately if the animal dies or is in danger of dying.
- d. The flocks are inspected and the exposed, low exposure, and high-risk animals are officially identified, exposed female sheep and high-risk sheep that the owner intends to retain are third eyelid tested and genotyped (exposed and high risk animals that have lambed or kidded that the owner does not want to retain should be tested at slaughter/necropsy). An exposed and/or test status is designated and the status opened in the Scrapie National Generic Database. Individual records are made for each exposed, low exposure, and high-risk animal in the database. The exposed and high-risk animals are restricted until the testing is completed and

the flock and individual animal statuses are determined. All animals that are determined to be high risk or exposed must be maintained on the premises unless moved in accordance with 9 CFR, part 79.

- e. If all the exposed animals are third eyelid tested and the high risk animals are euthanized and submitted for testing, and found negative the flock will be not be designated exposed. Animals that are euthanized for testing should be indemnified or purchased for diagnostic reasons.
- f. If one or more female high-risk animals that may have lambed in the flock are unavailable sheep born after the introduction of the high-risk animal(s) into the flock will be genotyped. All of these sheep that test QQ at codon 171 will be tested 18 months after the female high risk animal last lambed or resided in the flock that are at least 14 months of age at time of the test using the third eyelid or necropsy test. These sheep and female goats born after acquisition of the high risk animal should not be moved except in order to be tested at slaughter until the testing is completed. (Genotype testing on codon 171, and third eyelid testing have not been validated in goats). If all the exposed and high risk sheep are third eyelid tested and the high risk animals that can not be tested using the third eyelid test are euthanized and submitted for testing, and found negative the flock will be put on a PEMMP that requires the testing of any retained high risk animals when they die or are culled. If any female QQ high-risk sheep or female exposed goats are retained, the PEMMP will also require the testing of all animals born after the high risk animal was introduced that are found dead at over 18 months of age.
- g. Owners of high-risk animal(s) that do not submit them for testing when they die or are culled will be designated non-compliant flocks. Owners of high risk and exposed animal(s) that do not make them available for third eyelid or genotype testing will be designated non-compliant flocks.
- h. The PEMMP for flocks that contain high risk animals that have lambed that have not tested negative on a third eyelid or necropsy test shall restrict the movement of animals to slaughter only.

#### **E. Role of the Designated Scrapie Epidemiologist (DSE)**

1. DSEs will be nominated in accordance with 9 CFR 54 and VS Memorandum 557.3.
2. The DSE shall:
  - a. Ensure that a complete epidemiological investigation is completed for each infected, source, or exposed flock including the tracing of all exposed and/or high risk animals and that the completed investigation is forwarded to the regional and nation epidemiologists;
  - b. Designate the status of each animal in, or removed from, a scrapie infected or

- source flock in accordance with 9 CFR 79;
- c. Ensure that all required information is entered into the National Scrapie Database within 15 working days of receipt except for down grades in status that must be posted within 5 working days and ensuring that the information is complete and accurate;
  - d. Review and approve all flock plans;
  - e. Notify the national scrapie epidemiologist of any animals that are being considered for indemnification or for purchase for diagnostic purposes so that they can be made available to researchers in accordance with APHIS policy.
  - f. Coordinate slaughter surveillance activities for the State unless a separate slaughter coordinator has been designated.
  - g. Redesignate an animal designated a high-risk animal as an exposed animal in accordance with 9 CFR part 79 and applicable VS memorandums.
    - a. Male sheep that test RR at codon 171 may be reclassified as exposed.
  - h. Remove the suspect animal designation from an animal that has tested positive for scrapie or for the protease resistant protein associated with scrapie on an unofficial test if:
    - In consultation with a regional or national scrapie epidemiologist, it is determined that the unofficial test lacks scientific basis;
    - The animal is necropsied and tests negative on an official test;
    - The animal is subjected to an official live animal test at over 18 months of age; or
    - An epidemiological investigation shows that the animal is unlikely to be infected and an official live animal test cannot be done due to lack of sufficient tissue.
  - i. Remove the suspect animal designation from an animal that tested positive on a live-animal screening test based on an epidemiological investigation which includes additional official testing of the suspect animal and, when appropriate, animals that have been commingled with the suspect animal. The animal may be redesignated if it is necropsied and tests negative on an official test;
  - j. Determine what, if any, testing is needed to determine the status of an exposed flock based on an epidemiological investigation and the flock's management system. Please note that:
    - High risk or exposed animals that have not lambed in flock may be destroyed without test if (1) testing them can not result in the designation of additional high risk animals and (2) the animal or its tissues are not needed for developmental work or research.

- High-risk female animals that may be reclassified exposed based on genotype that have lambled or that the producer wishes to retain shall be genotyped.
  - High-risk male animals that the producer wishes to retain shall be genotyped. If their status may result in the designation of additional high-risk animals they will be third eyelid tested and submitted for necropsy when they die or are culled.
  - High-risk and exposed animals that the producer does not want to retain will be tested at necropsy if such testing may result in additional animals being designated high risk.
  - High-risk and exposed animals that the owner wishes to retain will be third eyelid tested. High-risk animals for which adequate tissue cannot be collected for a third eyelid test shall be tested at necropsy.
  - Flocks in which a high-risk or suspect animal lambled that is not available for test; third eyelid or necropsy test any QQ sheep and necropsy test any goat that was born during the same lambing season.
- k. Release the infected or source flock status of a flock upon determining that the premises was depopulated and has remained vacant of sheep and goats for five years and that the owner does not own or have control over any sheep or goat that were exposed to the premises or to animals from the premises.

In addition to the above responsibilities, a DSE may:

- a. Remove the exposed flock designation after completing an epidemiological investigation or upon completion of a post-exposure management and monitoring plan. As part of the epidemiological investigation the DSE may conduct testing of animals if he or she determines such testing is needed to properly redesignate the flock. The DSE will select animals for testing in a manner that will provide a 95 percent confidence of detecting scrapie at a prevalence of 1 percent or, when flock records are adequate and all exposed animals that lambled in the flock are available for testing, may limit the testing to all exposed and suspect animals. Testing may include live-animal testing using a live-animal official test, an official genotype test, the culling and postmortem examination and testing of genetically susceptible animals in the flock that cannot be evaluated by a live animal test, postmortem examination and testing of animals found dead or cull animals at slaughter, and the euthanasia and post mortem testing of any or all exposed or suspect animals.
- b. Redesignate an exposed flock as a noncompliant flock if the owner fails to make

- his animals available for testing within 60 days of notification or as mutually agreed or fails to submit required postmortem samples.
- c. Based on an epidemiological investigation and testing, redesignate an infected flock or source flock as an exposed flock. The DSE may only use this option when the epidemiological investigation reveals that the scrapie exposure was minor or could not be confirmed due to inadequate records. The DSE will select animals for testing in a manner that will provide a 95 percent confidence of detecting scrapie at a prevalence of 1 percent or, when flock records are adequate and all exposed animals that lambed in the flock are available for testing, may limit the testing to all exposed and suspect animals. Testing may include live-animal testing using a live-animal official test, an official genotype test, the culling and postmortem examination and testing of genetically susceptible animals in the flock that cannot be evaluated by a live animal test, and postmortem examination and testing of animals found dead or cull animals at slaughter. Infected or source flocks that are redesignated as exposed flocks must complete a post exposure monitoring and management plan. If an owner does not make his or her animals available for testing within 60 days of notification or as mutually agreed or fails to submit required postmortem samples, the flock designation will remain unchanged.
  - d. Remove the noncompliant flock designation after reviewing any required testing of the flock and determining that the flock has complied with the required testing or no longer meets the definition of a noncompliant flock.
  - e. Redesignate an exposed animal, exposed flock, or infected flock by removing that designation after completing an epidemiological investigation and determining that the exposure was limited to a scrapie-positive male animal that was not born in the flock (the owner must have adequate records and animal identification to show that the scrapie-positive male animal was purchased)
  - f. Redesignate an exposed animal a low exposure animal upon completion of an epidemiological investigation and the determination that the animal was exposed in a way that was unlikely to transmit scrapie, and officially identifying the animal or animals that may have been exposed to the lambing, kidding, abortion or vaginal discharge of a positive animal shall not be redesignated.

## **Part VIII: Flock Cleanup Plans**

### **A. Movement Restrictions**

No sexually intact animal will be permitted to move from an infected or source flock except under permit to slaughter, or to a research or diagnostic facility until a standard or pilot flock plan agreement has been signed. The movement restrictions on the flock and criteria for release of these restrictions will be specified as part of the flock plan, or post exposure monitoring and management plan. Sheep from flocks on approved pilot project flock plans written in accordance with 9 CFR 54 that are not high risk, scrapie-positive, or suspect animals, may be moved under the terms specified in the plan which must meet or exceed the 9 CFR requirements for exposed animals.

1. High risk animals must be retained on the premises unless the animal is moved under permit to slaughter or to a research or diagnostic facility and will be submitted for testing when they die.
2. Exposed animals may be moved only as permitted under 9 CFR and State regulations.
3. Animals that do not meet the definition of exposed are generally free to move unrestricted once the flock plan is completed. However, pilot flock plans and standard flock plans should restrict genetically more susceptible animals in cases where heavy premise contamination was likely to have occurred or where adequate cleaning and disinfection of the lambing areas was not possible.

### **B. Providing Services to Livestock Owners**

Program services may be rendered without expense to the livestock owner. However, owners are responsible for providing facilities and for handling their animals. Program administrators may contract with accredited veterinarians, para-professionals, other State and Federal agencies, or the management of privately owned firms, as needed, to assist State and Federal animal health personnel in collecting blood or tissue samples, in identifying animals, and in performing other specified activities.

### **C. Requirements for flock plans and post-exposure management and monitoring plans.**

1. The owner of the flock or his or her agent must identify all animals 1 year of age or over within the flock. All animals less than one year of age must be identified when a change of ownership occurs, with the exception of those animals under one year of age moving within slaughter channels that must be identified in accordance with CFR 79.2 and 79.3. The form of identification must be an electronic implant,



flank tattoo, ear tattoo, or tamper-resistant eartag approved for this use by APHIS. Goats may use a tail fold tattoo. The official identification must provide a unique identification number that is applied by the flock owner or their agent, and must be linked to the flock in the National Scrapie Database.

2. Upon request by a State or APHIS representative, the owner of the flock or their agent must have an accredited veterinarian collect tissues from animals for scrapie diagnostic purposes and submit them to a laboratory designated by a State or APHIS representative.
3. Upon request by a State or APHIS representative, the owner of the flock their agent must make animals in the flock and the required records available for inspection or testing.
4. The owner of the flock or their agent must meet necessary requirements of the State and/or APHIS to monitor for scrapie, prevent its recurrence, and prevent its spread to other flocks. These other requirements may include, but are not limited to:
  - a. Utilization of a live-animal test;
  - b. Restrictions on animals that may be moved from the flock;
  - c. Segregated lambing;
  - d. Cleaning and disinfection of lambing facilities; and/or,
  - e. Education of the owner of the flock and personnel working with the flock in techniques to recognize clinical signs of scrapie and to control the spread of scrapie.
5. The owner of the flock or their agent must immediately report the following animals to a State or APHIS representative, or an accredited veterinarian, and not remove them from a flock without written permission of a State or APHIS representative:
  - a. Any sheep or goat exhibiting weight loss despite retention of appetite; behavioral abnormalities; pruritus (itching); wool pulling; biting at legs or side; lip smacking; motor abnormalities such as incoordination, high stepping gait of forelimbs, bunny hop movement of rear legs, swaying of back end; increased sensitivity to noise and sudden movement; tremor, “star gazing,” head pressing, recumbency, or other signs of neurological disease or chronic wasting illness; and
  - b. Any sheep or goat in the flock that has tested positive for scrapie or for the proteinase resistant protein associated with scrapie on a live-animal screening test or any other test.
6. The following are the requirements for flock plans only:
  - a. An epidemiological investigation must be conducted to identify high-risk and exposed animals that currently reside in the flock or that previously resided in the flock, and all high-risk animals, scrapie-positive animals, and suspect animals must be removed from the flock. The animals must be removed either by

movement to an approved research facility or by euthanization and disposal of the carcasses by burial, incineration, or other methods in accordance with local, State, and Federal laws, or, in the case of high-risk animals, by movement to slaughter in accordance with the provisions of 9 CFR 79, or upon request in individual cases by another means determined by the Administrator to be sufficient to prevent the spread of scrapie.

b. The premises of a flock under a flock plan must be cleaned and disinfected in accordance with 9 CFR 54.7(e). Additional guidance on acceptable means of cleaning and disinfection is also available in Appendix A. Premises or portions of premises may be exempted from the cleaning and disinfecting requirements if a DSE determines, based on epidemiological investigation, that cleaning and disinfection of such buildings, holding facilities, conveyances, or other materials on the premises will not significantly reduce the risk of the spread of scrapie, either because effective disinfection is not possible, or because the normal operations on the premises prevent transmission of scrapie. No area where a scrapie-positive animals lambled or aborted may be exempted.

c. The owner of the flock, or their agent, must request breed associations and registries, livestock markets, and packers to disclose records to State or APHIS representatives to be used to identify source flocks, and trace exposed animals, including high-risk animals.

d. The flock owner must agree to conduct post-exposure management and monitoring.

7. The following are the requirements for post-exposure management and monitoring plans only. Please note that the plan must require that a State or APHIS representative inspect the flock and flock records at least once every 12 months. The owner of the flock or their agent must maintain, and keep records for 5 years on each animal, regardless of the reason it was removed from the flock. Recorded must be the following:

- a. Any identifying marks or tags present on the animal, including the animal's official identification number, and any secondary form of identification the owner of the flock chooses;
- b. Sex, year of birth, breed, and when possible, sire, dam, and offspring of the animal;
- c. Date of acquisition and previous flock, if the animal was not born in the flock; and,
- d. Disposition of the animal, including the date and cause of death, if known, or date of removal from the flock and name and address of the person to whom the animal was transferred.

8. Modification of flock plans and post-exposure management and monitoring plans. A DSE may modify the requirements of a flock plan or post-exposure management and

monitoring plan to accommodate the situation of a particular flock if the modified plan requires:

- a. That a State or APHIS representative inspect the flock, records at least once every 12 months;
  - b. The animals are tested at a level that will result in 99 percent confidence of detecting a 1 percent prevalence in the flock (for flock plans only);
  - c. Identification by approved method all animals leaving the premises of the flock, for purposes other than slaughter, and of all animals over 18 months of age (as evidenced by the eruption of the second incisor) in slaughter channels; and,
  - d. Record keeping including:
    - i. For acquired animals, the date of acquisition, name and address of the person from whom the animal was acquired, any identifying marks and all identification.
    - ii. For animals leaving the premises of the flock, the disposition of the animal, including, for those animals that are required to be identified, any identifying marks and all identification, the date and cause of death, if known, or date of removal from the flock, and name and address of the person to whom the animal was transferred.
    - iii. Maintenance of these records for 5 years.
  - e. Requirements equivalent to those contained in paragraphs (b), (c), and (d), of this section.
9. Post-exposure management and monitoring plans for exposed flocks that were not source flocks and in which a scrapie infected animal did not lamb. A DSE shall determine the testing and monitoring requirements for these flocks based on the exposure risk of the individual flock.
  10. Waiver of requirements for scrapie control pilot projects. The Administrator may waive the following requirements of this part for participants in a scrapie control pilot project by recording the requirements waived in the scrapie control pilot project plan:
    - a. The determination that an animal is a high-risk animal, if the scrapie control pilot project plan contains testing or other procedures that indicate that an animal, despite meeting the definition of high-risk animal, is unlikely to spread scrapie;
    - b. The requirement that high-risk animals must be removed from a flock if the scrapie control pilot project plan contains alternative procedures to prevent the further spread of scrapie without removing high-risk animals from the flock.
  11. Minimum Requirements for Pilot Flock Plans. To qualify for a pilot project a flock must reside in a State that has signed an agreement with APHIS to conduct a scrapie control pilot project. To qualify, a pilot project must advance knowledge with regard to scrapie control and must provide adequate safeguards to prevent the spread of scrapie. These will include:

- a. Restriction of all high-risk animals to the premises except for movement to slaughter;
  - b. Necropsy and testing of all animals that die over 14 months of age, particularly high-risk animals;
  - c. Third eyelid testing of all exposed animals over 14 months of age, or when they reach 14 months of age;
  - d. Retest of all test eligible animals 18 months after the last known exposure to scrapie;
  - e. Removal of all test positive animals;
  - f. Restrictions on the movements of other animals out of the flock except to slaughter unless testing or other methods have been used to insure that they are low risk for spreading scrapie; and,
  - g. Genotype used as a selection criteria.
12. Cleaning and Disinfecting. Specific cleaning and disinfection requirements for a flock should be determined by the VMO on site and documented in the flock plan. Every effort should be made to remove all organic material from any area where ewes have lambed, or where ewes or lambs are housed or congregate within 60 days of birth. These areas should be disinfected whenever the surfaces will permit in accordance with 9 CFR 54.7(e). Any equipment that has come in contact with parturient or post parturient ewes must be cleaned and disinfected.

A flock in which the lambing area is likely to have been contaminated may not be released from flock plan status unless confined lambing areas are thoroughly cleaned and disinfected, or converted to another use that prevents the access of sheep to the facility.

Equipment belonging to an infected or source flock should not be shared with another flock. Any equipment that is likely to have been contaminated must be clean and disinfected.

Transport vehicles must be cleaned and disinfected after hauling female suspect or exposed animals that are parturient or that have a visible vaginal discharge

Additional cleaning and disinfection deemed necessary by the State or APHIS may be required.

Other requirements that should be included when practical include the following:

- Use of contemporary lambing groups;
- Disposal of placenta and associated fluids as soon as possible after lambing;
- Routine cleaning/disinfection of lambing areas and equipment;

- Use of normal hygienic procedures, i.e., wash and disinfect boots and remove the outer layer of clothing, when leaving the farm premises.

## **IX. Diagnostic Laboratory Approval Procedures and Test Interpretation**

Laboratories will be approved in accordance with 9 CFR and applicable VS memorandums.

### **Part X. Reports**

Reports will be made in accordance 9 CFR and applicable VS memorandums. Also see part V.C.